UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,259	02/07/2001	Cristobal Guillermo dos Remedios	13388	4496

7590 09/23/2004

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,259	REMEDIOS ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-33* is/are pending in the application.

4a) Of the above claim(s) *13-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-9, 11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 7/8/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2, 10 are cancelled.

2. Currently, claims 1, 3-9, 11-12 are under examination. Claims 13-33 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-9, 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 confusing because it is unclear how the assay is performed. Claim 1 recites contacting binding partners either before, during or after said partners have formed a binding partnership with a sample containing a toxicant, and screening for either dissociation of binding between said binding partners, or inhibition or binding between said binding partners, it is unclear how this is performed. First, it is unclear what is meant by "binding partnership", do the binding partners bind to the toxicant in the sample? According to the preamble, the binding partners appears to have ability to bind

each other, and the assay is one that screens for any compounds that have a toxic effect on this binding relationship, either by inhibiting the binding of the partners to each other, or by dissociating the binding partners form each other. According to claim 1, for example, the binding partners are allowed to "form a binding partnership" with the sample containing the toxicant, assuming that this means that the binding partners bind to the toxicant, how does this binding then allows for detecting either dissociation or inhibition of the partners to each other?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 3, 4, 7, 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Omura et al. (Annual Meeting of Soc Chem Eng., March 25, 1999, Japan, English Translation).

Omura et al. teach a method of detecting environmental toxicant, e.g. hormone disruptor, using fluorescence technology. Omura et al. teach immobilized estrogen receptor, i.e. binding partner, on a plastic beads, e.g. polystyrene, and then add fluorescent labeled estradiol labeled BSA to form binding partnership with the binding partner (See English Abstract, second paragraph, Method). Omura et al. teach that adding potential hormone disruptor toxicant would then compete, i.e. effect dissociation binding, with the binding and the reduction of fluorescence intensity can be detected (See Abstract, Method). With respect to claim 7, the binding partner estrogen receptor is a large protein containing sulfhydryl group in its structure.

1. Claims 1, 3, 4, 5, 6, 7 and 11 are rejected under 35 U.S.C. 102 (e) as anticipated by Wu et al.. (USP 6207391)

Wu et al. teach an assay for screening compounds of modulating protein-receptor binding based on increase or decrease of the binding in comparison with the binding absence of the modulators. (claim 1) Wu's method is applicable in pharmaceutical industry (See Introduction Background). It is clear that Wu's method encompassed an aquatic environment since "aquatic" pertaining to water-related environment which is disclosed in the performing process (Example 1-4) Wu et al. also teach immobilizing binding partner to a solid support, i.e. polystyrene (Col. 15, line 53-55). Wu et al. teach the binding partners including proteins, receptors, enzymes, and substrates of enzymes. (claim 1, Col. 4, line 5-15) The proteins, receptors or enzymes taught by Wu et al. all contain sulfhydryl group for folding.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-7, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (J Occupational Med 1986 Vol. 28, page 589) in view of Ngo et al. (US 4977077).

Pierce teaches a method of detecting environmental contaminants by enzyme-mediated immunoassay. Pierce teaches using a binding partner for the toxicant forming binding partnership with the labeled toxicant in a system (See page 590, Right column, last paragraph). If there exists toxicant in the sample, then competition would take place and reduce the label intensity (See supra). However, Pierce does not teach specifically immobilized the binding partner, e.g. antibody, on a solid support. Ngo et al. teach a similar method of detecting an analyte in a sample by immobilizing antibody on a solid support, e.g. glass or plastic beads, for competition assay of the analtye (Col. 2, line 40-55). Ngo et al. teach that the immobilization of antibody provides advantages of increasing sensitivity (Col. 2, line 31-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Pierce with the solid support to immobilize the binding partner such as antibody as taught by Ngo et al. since the technology is well-known in the art for increasing sensitivity in the immunoassay.

5. Claims 8-9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omura et al. in view of Kekic et al. (Electrophoresis 1999 20: 2053) and Ngo et al.

Omura et al. reference has been discussed but is silent in using actin or its binding protein as the binding partner for detecting toxicants. Furthermore, Omura et al. does not specifically teach labeling on the binding partner for detection. Kekic et al. teach that the actin and its binding protein, e.g. cofilin, can be used to detect environmental metals, such as Cd, Cu, Hg or Zn, or other organic chemicals (See Abstract; Table 2). Ngo et al. teach immobilizing a labeled binding partner antibody on the solid support to detect the analtye of interest in a sample (Col. 4, line 40-50). Therefore, it would have been obvious to have motivated one skilled in the art at the time the invention was made to use the labeled actins and cofilin as the binding partner as taught by Kekic and Ngo et al. with reasonable expectation of success to detect environmental toxicants because Kekic disclose actins/cofilin are good markers for environmental toxicants, Ngo et al. teach labeling antibody for competition assay of analyte, and both references are within analogous art to motivate one artisan to incorporate into its immunoassay for environmental monitoring.

Response to Applicant's Arguments

6. Applicant argues that (1) Wu et al. reference does not teach a method for the identification of a "toxicant"; and (2) Wu et al. reference is for identifying therapeutics rather than aquatic, terrestrial, gaseous or industrial environmental toxicant. Applicant's arguments have been considered but are not persuasive.

Examiner had pointed out in the previous Office Action (October 28, 2003) that applicant defining toxicants as that "toxicants may or may not necessarily be "toxic" in the sense that they are capable of inducing death or a living organism or inducing one or more mutations in the genome..... *Toxicants may also vary their toxicity depending on concentration or time of exposure.*" (See page 7, line 21-24) Therapeutics, many times indeed could become "toxic", e.g. inhibit cellular protein binding, at a higher concentration or prolonged time of exposure. Therefore, Wu et al. teachings encompass the instant inventions.

Second, there is no definition or working example as to clarify the metes and bounds of the preamble "aquatic, terrestrial, gaseous or industrial environmental sample", examiner takes the position in reliance with common dictionary which defines the "aquatic" as "*of or in water*" and "industrial" as "*relating or derived from industry*; or having highly developed in industry" (See Webster's II dictionary, 1984 The Riverside Publishing Company; page 120, 625). It is inherent that nearly every assay requires "water" and pharmaceutical development is a highly developed industry. Therefore, under Wu's teachings, the instant invention is rendered anticipated accordingly.

Conclusion

1. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

September 16, 2004

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
9/20/04